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| 10/068,633 | 02/05/2002 | Yusuf Ali | GOJO.01211 | 8088 |

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| EXAMINER | |
|---|---|
| KIM, VICKIE Y | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1618 | |

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/068,633 | ALI ET AL. | |
| | Examiner | Art Unit | |
| | Vickie Kim | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3,5-9,12 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-9,12 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



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## DETAILED ACTION

1. In view of the Appeal Brief filed on 8/27/04, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

### *Specification*

2. The amendment filed Aug 27, 20041 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the paragraph "lactic acid..... sodium acetate" added in page 8(beginning on line 16), except the species that are originally disclosed(i.e. sodium hydroxide, potassium hydroxide, ammonium hydroxide, magnesium hydroxide).

Applicant is required to cancel the new matter in the reply to this Office Action.

### *Claim Rejections - 35 USC § 112*

### *New Matter*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art towhich it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth thebest mode contemplated by the inventor of carrying out his invention.**

2. The claims 1, 3, 5-6, 8, 12 are rejected as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. The claims are drawn to a composition comprising an effective amount of a neutralizer designated by the FDA as of FEB. 5, 2002, to neutralize the thickening agent. The specification as originally filed specifically provides a generic description which supports the neutralizer designated by the FDA. Therefore, the claims fail to comply with the written description requirement. It is not certain what are the compounds are included in the FDA guideline and whether all the compounds disclosed in FDA guideline is in fact under the possession of inventor(s).

### *112 Rejections - 1st*

### *Scope of Enablement*

1. Claims 5-6, 20-22, and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to use the invention commensurate in scope with these claims because the specification, while being enabling for a composition comprising using certain neutralizers such as sodium hydroxide, potassium hydroxide, ammonium hydroxide or magnesium hydroxide, does not reasonably provide enablement for a composition comprising any newly added neutralizer that is designated by the FDA as of FEB.5, 2002(see amendment for specific species Aug . 27, 2004). Thus, a composition amended is not commensurated in the scope with the said claims.

Attention is directed to In re Wands, 8 USPQ 1400 (CAFC 1988) at 1404 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls) at 547 the court recited eight factors:

1) *The nature of the invention:*

The instant invention is related to a composition comprising (i) an aliphatic alcohol, (ii) a carbomer polymer as thickening agent (iii) neutralizing agent.

2) *The state of the prior art:*

As stated in the instant specification, the state of art recognizes that all neutralizers are not sharing same chemical or physical characteristics(e.g. acidity), see Miyata(US5837735). For example, US'735(at col. 3, lines 20-30 and col. 4, lines 5-11) teaches certain basic neutralizers are used to neutralize carbomers due to their weak acidity.

It is generally acknowledged in the art that chemical reaction (interaction between two compounds) is influenced by different reaction(Vandewaals, ionic, covalent, etc) because all the possible reactions are unpredictable.

3) *The relative skill of those in the art:*

The relative skill of the those in the art is high.

4) *The predictability of the art:*

The high degree of unpredictability in organic chemistry is well known in the art. A slight change in the structure of the compound would drastically change its selectivity for the reaction and bonding types and furthermore, the composition containing multiple active and inactive ingredients of different chemical structures and modes of actions, their interactions, co-actions, e.g. synergism etc. is extremely unpredictable.

5) *The breadth of the claims:*

Applicant's amendment, now including various types of chemical compounds as neutralizers would be useful for neutralizing carbomers does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability and the limited working examples.

6) *The amount of guidance/working examples:*

The specification lacks in providing any working examples against all types of neutralizers as amended. The specification provides few working examples using basic substances(e.g. sodium hydroxide, potassium hydroxide, ammonium hydroxide or magnesium hydroxide ), see pages 3 and 13. Furthermore, the exemplified compounds are not acid substances whereas newly added compounds are not only basic but also

acidic substances, and therefore, the specification has only enabled the neutralization of carbomer using basic neutralizers but not any other substances.

7) *Quantitation of undue experimentation.*

Since insufficient teaching and guidance have been provided in the specification, one of ordinary skill in the art, even with high degree of skill, would not be able to use the composition as claimed without undue experimentation except for a composition comprising certain neutralizing substances such as sodium hydroxide, potassium hydroxide, ammonium hydroxide or magnesium hydroxide to neutralize carbomer that is characterized in weak acids.

The true fact of the state of the art in cancer therapy is expressed well, "The significance of particular interaction(i.e. neutralization) for modifying its certain characteristics cannot be predicted a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study " to determine the efficacy.

***112 Rejection, 2nd***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

4. Claims 1, 3, 5-6, 8, 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A FDA guideline is recited in the instant claims to identify or describe a particular material(i.e. neutralizer). However, the claim does not comply with the requirement of 112, second paragraph. As evidenced by applicant's admission, FDA guideline is not permenant and thus, the scope of claim is not clear,rather uncertain. Although FDA recognizes a neutralizer that is generally recognized as safe, the standard for safety is not consistent nor permanent. Thus, the FDA guideline can not be incorporated into the claims ton describe essential subject matter. Furthermore, MPEP states that the attempt to incorporate FDA guideline into the claims is improper because essential material may not be incorporated by reference to any publication which is to issue as a US patent, see MPEP 608.01(p). Neutralizer is considered to be "essential material" where it should have not been incorporated by FDA guideline.

The claims should have been particularly and distinctively pointing out the subject matter and every effort made to prevent their use in any manner which might adversely affect their validity. Thus, the claims 1,3, 5-6 and 8, 12 are properly included in this rejection.

***Claim Rejections - 35 USC § 102/103***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3, 5, 6, 7, 9 and 12 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Samour et al(US 5,976,566) , or alternatively , under U.S.C. 103(a) as being unpatentable over Samour et al(US 5,976,566).

Samour et al(US'566 hereinafter) teach a topical alcoholic gel 55-70% ethanol, isopropanol or mixture thereof, 0-2% of cellulosic thickener, a base to adjust the pH, and see col. 4, lines 30-35. US'566 also teaches incorporation of an appropriate base such as sod. Hydroxide to neutralize the formulation, see col. 3, lines 40-49. US'566 further teaches carbopol® as a thickening agent, see col. 9, lines 1-7.

As to claim 12, US'566 teaches a specific viscosity in the range about from 1000 to 65000 centipose at 70 farenheit, the viscosity recited in preamble would have been inherently possessed by the composition taught by the patent because all the ingredients required by the claims are also included in the patented composition. One would have been envisaged that both patented composition and the claimed composition comprising an aliphatic alcohol, carbomer, and a neutralizing agent would have same viscosity, absent evidence to the contrary. It is also conventional knowledge* that the viscosity of topical formulations including gel would have 1000 to 65000 centiposes as well as evidenced by applicant's own admission(in light of specification, see page 12, lines 9-12), and thus, the gel composition taught in US'566 patent would have naturally embraced the scope of the instant claims(* see US 4970220, at col. 9, lines 30-35 , extrinsic evidence for supporting this examiner's statement, for example, US'220 teaches, " .... The viscosity of carious personal care

compositions may vary widely. However, for easy dispersing and enhanced stability it is generally preferred to employ compositions at viscosities from 2000 to 20,000 cps".

Antimicrobial activity and desity recited in preamble also inherently met by the composition taught in US'566 patent because all the essential elements required by the instant claims are same. For example, it is well known in the art aliphatic alcohol(e.g. ethanol or isopropanol) has antimicrobial activity inherently and thus, the claims are met.

All the critical elements required by the instant claims are well taught in the cited reference and thus, the claimed subject matter is not patentably distinct over the prior art of the record.

In any event that the viscosity, or density is different than that of patented composition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify and employ claimed viscosity or density to produce in order to determine most effective, stable composition and the technique and skills are well within skill level of the artisan having ordinary skill in the art and the modification are routinely practiced , and thus obvious, absent evidence to the contrary. The said variation are considered to be minor and does not render the claims patentably distinct over the prior art of the record.

7. Claims 1, 3, 5, 6, 7, 9 and 12 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by, or alternatively,under U.S.C. 103(a) as being unpatentable over Mckenzie et al(US 5747021).

Mckenzie et al(US '021, hereinafter) teach a transparent topical composition(e.g. gel) comprising isopropanol, varbomer and sodium hydroxide(0.1%), see col.3, lines 5-14. patented claim 7 recites all the critical elements required by the instant claims such as 30-70% of isopropyl alcohol, 0.25-1.75% carbomer.

As to claim 12, US'021 teaches glycerin or PEG-8 for "slip" effect which is referring to moisturizer or emollients in the field. Thus, one would have readily envisaged the claimed composition from Mckenzie(US'021)' teaching

As mentioned earlier in 102/103 rejection over Samour's(US566, viscosity, density and antimicrobial activity are inherently met by the composition taught in US'021 patent because all the essential elements required by the instant claims are substantially same. All the critical elements required by the instant claims are well taught in the cited reference and thus, the claimed subject matter is not patentably distinct over the prior art of the record.

In any event that the viscosity, or density is different than that of patented composition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify and employ claimed viscosity or density to produce in order to determine most effective, stable composition and the technique and skills are well within skill level of the artisan having ordinary skill in the art and the modification are routinely practiced , and thus obvious, absent evidence to the contrary.

As to claim 3, US'021 exemplfies isopropanol as lower aliphatic alcohol but not explicitly mention about ethanol. However, ethanol and isopropanol are particularly well known alcohols ( available as over the counter product). The said variations and

substitution are considered to be minor and does not render the claims patentably distinct over the prior art of the record.

***Claim Rejections - 35 USC § 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samour(US'566) or Mckenzie(US'021) in view of BF Goodrich Tech. Disclosure("neutralizing carbopol...", 1998).

The rejection is substantially same as one previously issued. Detailed rejection should be referred to one issued on 12/22/03.

***Conclusion***

1. No claim is allowed.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
Primary Patent Examiner
May 16, 2005
Art unit 1618